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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,728	03/01/2000	Thomas O Daniel	1242/12/2	2723

25297 7590 09/06/2002

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/06/2002

78

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/516,728

Applicant(s)

DANIEL ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8 and 10-55 is/are pending in the application.
- 4a) Of the above claim(s) 15-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8, 10-14 and 45-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. The examiner of the application has changed. This case has now been transferred as of 8/29/02. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Christopher Yaen, Group Art Unit 1642.

2. The amendment filed 6/4/02 is acknowledged and entered into the record. Claims 1 and 9 have been canceled without prejudice, claims 45-55 have been newly added, claims 2-8 and 10-55 are pending. Claims 15-44 are withdrawn from consideration as being drawn to a non-elected invention. Therefore, claims 2-8, 10-14, and 45-55 are examined on the merits.

3. This application contains claims 15-44 drawn to an invention nonelected without traverse in Paper No. 13. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections Withdrawn

4. The rejection of claims 6 and 12 under 35 USC 112, 2nd paragraph, as being indefinite in the recitation of the phrase "immunoreaction characteristics," is **withdrawn**, in view of the amendments set forth by the applicant.

5. The rejection of claims 1 and 9 under 35 USC 112, 2nd paragraph, as being indefinite, is **withdrawn**, in light of the cancellation of these claims.

6. The rejection of claim 1, 4, 8, and 14 under 35 USC 102(b), as being anticipated by Tonks *et al*, is **withdrawn**, in light of the cancellation of the claim.

Claims Rejections Maintained

7. The rejection of claims 2-4, 8-11 and dependent claims thereof under 35 USC 112, 2nd paragraph, as being indefinite in the recitation of the term "preferentially", is ***maintained***, for the reasons of record. Applicant's remarks and arguments have been carefully considered, but are not found persuasive for the following reasons. Applicant argues that one of skill in the art would readily be able to understand the term, because it is an art recognized term when referring to antibodies. This is not found persuasive because the term does not specifically localize the binding epitope of the antibody.

OK Further, because the metes and bounds of this term does not specify with certainty where the epitope is, one of skill would find it hard to pinpoint the exact location within the ectodomain of this protein to find the exact epitope. Furthermore, an antibody, (i.e polyclonals) that recognized ectodomains and cytoplasmic domains would read on the term "preferentially," because polyclonals can mostly comprise antibodies that bind to the ectodomain and some that bind cytoplasmically.

UD 8. The rejection of claims 3, 10 and dependent claims thereof, under 35 USC 112, 2nd paragraph, as being indefinite in the recitation of the phrase, "analog sequence", is ***maintained***, for the reasons of record. Applicant's remarks and arguments were carefully considered, but are not found persuasive for the following reasons. Because the term can encompass a multitude of possible "analogs", one of skill in the art could not possibly know or understand the meaning or the exact "analog" to which the instant invention refers.

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9. The rejection of claims 4, 8, 14 and now newly applied to claims 2, 45 and 46 under 35 USC 102(b) is maintained for the reasons of record. Claims 2, 4, 8, 14, 45, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Tonks *et al* (WO 95/30008). Claims 2, 4, 8, 14, 45, and 46 are drawn to an antibody that binds to the ectodomain of ECRT/DEP-1, wherein the antibody is monoclonal, humanized, in a pharmaceutically acceptable excipient, and has activity in modulating angiogenesis.

Tonks *et al* teach an antibody that binds to DEP-1, which appears to be the same protein and has the same function as the protein described in the instant application. The disclosure of Tonks *et al* also teaches that the antibody can be used in a pharmaceutical capacity for the modulation of biological activities of DEP-1 protein. Since the antibody of Tonks *et al* is to be used in an in vivo capacity, presumably, the antibody will bind to the ectodomain of DEP-1 to modulate its activity. Furthermore, in the absence of any evidence to the contrary, since the ECRT/DEP-1 protein has been implicated in angiogenesis, the antibody disclosed by Tonks *et al* may also have activity in modulating angiogenesis.

10.

New Claim Rejections

Claim Rejections - 35 USC § 112

11. Claims 2-4, 6, 8, 10, 12-14, and 45-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

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invention. The written description in this case only sets forth an antibody that binds to EC RTP/DEP-1 and therefore the written description which read on fragments or derivatives of the antibody that binds to EC RTP/DEP-1 have not been described adequately to one of skill in the art.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of the antibody that binds to EC RTP/DEP-1, the skilled artisan cannot envision the detailed structure of the encompassed fragments or derivatives and therefore conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it or preparing such fragments or derivatives. The amino acid sequence itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. Although these court findings are drawn to DNA art, the findings are clearly applicable to the claimed proteins.

Furthermore, although drawn specifically to the DNA art the findings of *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412) are clearly applicable to the instant rejection. The court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Support for fragments and derivatives is provided in the specification on page 35-36, where it is taught that a fragment or derivative can be identical to the natural ligand or where one or more changes are made and it retains the ability to function as an ECRT/DEP-1 modulator. However, no disclosure, beyond the mere mention of fragments or derivatives is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only an antibody that binds to the ectodomain of ECRT/DEP-1 meets the written description provision of 35 USC 112, first paragraph.

Conclusion

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No claim is allowed. This action is made **non-final** in light of the new claim rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
September 3, 2002

Brenda Brumback
BRENDA BRUMBACK
Primary **PATENT EXAMINER**